

REMARKS

The above-captioned patent application has been carefully reviewed in light of the non-final Office Action to which this Amendment is responsive. Claims 1, 6 and 9 have been further amended in a concerted effort to distinctly point out and particularly point out the claimed subject matter of the pending application. Claim 17 has been canceled. It is believed that no new matter has been added.

Claims 1, 6, 9 and 11-17 are pending. The Examiner has maintained the rejection of pending Claims 1 and 6 based on previously cited prior art; namely, either Hughes or the combination of Treptow et al. and Lukacs et al. under 35 USC §103(a). In addition, Claims 9 and 12-17 have been rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully requests reconsideration based on the amended claims and the following discussion.

Applicant first refers to the prior art rejection of Claims 1 and 6 under 35 USC §103(a) as being unpatentable over Hughes (U.S. Patent No. 3,449,081).

As previously noted in prior correspondence and in order to successfully maintain a "*prima facie*" obviousness rejection under the Patent Statute, each and every claimed limitation must be found in or be suggested by the cited art, whether singly or in combination. Those limitations not found in or are suggested by the reference(s) must be commonly well known in the field of the invention to one of sufficient (i.e., ordinary) skill at the time thereof. Moreover, one should review the references in their entirety in making such a rejection in which the rejection should not be made based on advance knowledge (i.e., hindsight) of the present invention, especially in making prior art combinations of references. Put another way, there must be a reason somewhere in the prior art to make a purported combination.

The Examiner has opined that Hughes contains each and every claimed structural limitation of each of Claims 1 and 6. The Examiner has again noted that he believes Applicant's recitations to the fluid relate merely to those of "intended use" and therefore should carry no patentable weight in terms of the analysis. Applicant herein disagrees as it is believed a fluid is specifically and positively as a component part of each of Claims 1 and 6 and not merely serving to provide an intended use for the structure of the herein claimed metering tip. That is, the fluid is stated in each of the preamble and is relied upon throughout the entire body of Claims 1 and 6.

In an effort to advance prosecution with regard to these claims, Applicant has now amended each of Claims 1 and 6 to specifically recite the fluid as part of a claimed combination that comprises the metering tip and the fluid, which is now specifically recited as at least one a reagent and a body fluid (see paragraph [0003]). It is not believed any new matter has been added as Applicant has herein clarified the combination of already claimed elements.

Moreover, there are further distinguishing characteristics between the cited art and Claims 1 and 6. As previously noted by Applicant, it is not believed that the cap of Hughes describes or suggests an optical read window that includes the structure presently recited. To that end and according to the present invention, a quantity of fluid must be present within the metering tip itself to permit spectrophotometric optical analysis. The read window must permit such detection meaning that: i) the fluid should be contained within the element itself and ii) in a section that permits optical detection without distortion. The first goal is achieved by having the fluid actually retained within the transparent tip and the second goal is achieved by defining a section of the tip that can retain the fluid and also present no significant interruptions of entering and exiting light. The latter is further achieved by defining an axial cylindrical portion that is further defined by a substantially constant and planar (smooth) diameter. Each of the above are clearly shown in each of Figs. 11 and 12, wherein each illustrate a read window whether in the prior art or according to the present invention. Applicant has previously acknowledged that a "read window" as defined within a metering tip is not in and of itself the novel aspect of the present invention.

In Hughes, the cap covers a portion of the bottle 12, as clearly seen in each of Figs. 4 and 6 other than the cap portions that include the ring-like sections. The bottle therefore provides an additional layer of plastic that must be viewed through, wherein the fluid is not actually retained within the cap, but is rather retained in the bottle. Only in the portion of the cap having the ring-like sections is fluid actually retained in the cap. To that end, the cap is not functioning as a metering tip nor is the structure capable of performing the function unless the cap were to be used alone. Second, the cap requires screw threads in order to permit the cap to be attached to the bottle – see Fig. 4 of Hughes wherein screw threads are evident along the entire interior of the peripheral upper portion of the cap. Claims 1 and 6 specify the structure of the read window in terms of its internal diameter. As noted above, Hughes fails to include an axial cylindrical portion that defines a read window according to the present invention.

With regard to the combination of Lukacs et al. and Treptow et al. as to Claims 1 and 6, Applicant again believes there is insufficient motivation to make the purported combination. Lukacs et al. discloses a fluid dispensing member that includes a series of ring-like sections. The purpose of the ring-like sections is clearly articulated in this reference – that purpose being to accommodate containers of different size into which fluid is being dispensed. See col 2, lines 23-25 of Lukacs et al. Lukacs et al. fails to provide ring sections for purposes of reducing fluid oscillation and the fact that Applicant has determined that an arrangement that looks somewhat similar solves an entirely different and unrelated problem has been used against the Applicant for purposes of this examination. Treptow et al. also fails to discuss or describe these issues. Applicant does not disagree that this secondary reference describes a window for optical testing in general. No discussion is made concerning issues having to do with fluid oscillation or fluid dead volume, as now recited definitively according to Claims 1 and 6, respectively. There is insufficient motivation to combine references to create metering tips as specifically claimed herein. Moreover, structure is missing from both of the cited references with regard to Claim 6 in that Lukacs et al. fails to include a stepped area being disposed above the read window, this read window now being positively recited as having an interior diameter that is substantially constant and planar (smooth) over a cylindrical axial portion. Because neither reference includes this feature, there can be no “*prima facie*” obviousness rejection under the Statute. Reconsideration is respectfully requested.

Turning to the remaining outstanding rejection, the Examiner has rejected Claims 9 and 12-17 under 35 USC §112, first paragraph. With regard to the latter rejection and according to the Examiner, the claims contain subject matter which was not described in the specification in such a way that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It has been further noted in the Office Action that Claim 9 had been previously amended to include steps that were not previously or originally recited. Whether the claimed subject matter was originally claimed by Applicant is not the salient issue for a proper Section 112 analysis, but rather the issue is whether there is adequate support in the specification to prove that Applicant had knowledge of the claimed subject matter at the time of filing the application. As a matter of completeness, only Claims 1-5 are originally filed claims in the present application and therefore Applicant has a burden to prove support for all succeeding claim

amendments. To that end, Applicant had believed that each of the amendments had been thoroughly described in previous correspondence. However and to fully clarify this issue to the satisfaction of the Examiner, Applicant herein refers to Claim 9 and provides support in the application for all presently recited limitations. Similarly, Claims 12 – 17 are also similarly referred to in terms of their support, since each of these claims were also not included in the original claim set.

Claim 9 is now reproduced as follows:

Claim 9: A method for performing an optical read of dead volume of fluid in a metering tip, said method including the steps of:

i) attaching a metering tip to a metering apparatus (**discussion with regard to the attachment of a metering tip to a metering apparatus is known and acknowledged throughout the disclosure; see, for example, paragraphs [0003], [0004], [0005], [0006], and specifically paragraph [0022] and [0025] – note further that the use of a metering apparatus is referred to in terms of its removal therefrom in paragraph [0027] prior to sealing the tip**);

ii) aspirating a volume of fluid into said metering tip using said metering apparatus, said tip comprising at least one stepped area within the interior of the metering tip, each said at least one stepped area including a sharp diametrical edge at the junction of the surface of an interior region and surface of the stepped area, said surfaces being substantially orthogonal (**aspiration is acknowledged from the preceding and also in that Figs. 4-10 indicate tips with aspirated fluids therein, the geometry of the tips and the stepped areas is described in paragraph [0024]**);

iii) dispensing a portion, but not the entirety, of the volume of fluid from said metering tip through said lower tip opening wherein said dispensed portion of fluid is moved over the sharp diametrical edge of said at least one stepped area so as to latch a lower meniscus of the fluid passing said at least one stepped area and thereby reducing oscillation of the fluid in the metering tip (**see paragraph [0024] and Fig. 3**);

iv) drawing the remaining fluid in said metering tip upwardly and into an axial cylindrical section of said metering tip, said axial cylindrical portion being defined with a substantially constant planar internal diameter defining a read window wherein one of said at least one stepped areas is located above said read window, wherein said stepped area above said read window flattens the upper meniscus of a said retained volume of fluid (see paragraph [0028] that refers to drawing the “dead volume” of fluid, first referred to in paragraph [0026], and in which the stepped area that latches the meniscus of the dead volume is defined in paragraph [0030] and in which an optical “spectrophotometric” read is made in the read window 96 relative to the stepped area 92, see Fig. 12); and

v) optically reading the retained volume through said defined read window (see paragraph [0030] and Fig. 12).

Claims 12-16 are reproduced, as follows wherein the proper support is indicated in parentheses at the end of each clause. Claim 17 has been canceled.

Claim 12: A method as recited in Claim 9, including the additional step of sealing the lower tip opening of said metering tip prior to performing said reading step (**Support is found at paragraph [0028] in which it is noted that the dead volume is drawn into the nozzle and then the lower tip opening is sealed. The fluid is then read, as defined according to paragraphs [0029] and [0030]). Sealing is described at paragraph [0027] by “melting the tip of the nozzle 64” in which the “the sealed tip becomes a “cuvette” which can be stored.....for a later spectrophotometric read.”**

Claim 13. A method for reducing fluid oscillation for a fluid retained within a metering tip, said method including the steps of:

i) attaching a metering tip to a metering apparatus (see paragraph [0022] indicating use of the tip with clinical analyzers and in the Background portion in which metering mechanisms are previously described);

ii) aspirating an initial volume of fluid into said metering tip, said tip comprising a lower tip opening, an upper tip opening and an interior, said interior further comprising at least one stepped area, said at least one stepped area including a sharp diametrical edge at the junction of the surface of an interior region and the surface of the stepped area, said

surfaces being substantially orthogonal, said tip further including an axial cylindrical portion defined by a substantially constant planar interior diameter, thereby further defining a read window (**aspiration is inherent from use with metering apparatus and clinical analyzers, see Figs. 3 -10 in which fluid has been aspirated into tip for dispense thereof; geometry of tip stepped areas is described at paragraph [0024] and read window is evident from prior art Fig. 2 and from Fig. 12 (96)); and**

iii) dispensing fluid from said tip, wherein said dispensing step includes the step of moving a meniscus of fluid past the sharp diametrical edge thereby for latching the fluid, a meniscus of the fluid passing said at least one stepped area and thereby reducing oscillation of the fluid in the metering tip (**support provided for this subject matter at paragraph [0024]).**

Claim 14. A method as recited in Claim 13, wherein said method includes the step of dispensing retained fluid onto at least one reaction device, wherein said at least one stepped area is disposed proximate to said lower tip opening to latch a lower meniscus of dispensed fluid to reduce oscillations thereof during the dispense step (**support is found at paragraph [0024] and Figs. 4-10, indicating position of the stepped areas in relation to the lower tip opening).**

Claim 15. A method as recited in Claim 14, wherein said at least one stepped area includes a plurality of adjacent stepped areas disposed in relation to said lower tip opening (**support is found at paragraph [0024 and Figs. 4-10, indicating the position of the stepped areas in relation to the lower tip opening).**

Claim 16. A method as recited in Claim 13, including the additional steps of:

dispensing portions of the initial volume of aspirated fluid onto at least one reaction device (**support for dispense provided at paragraphs [0024, 0025] and in which it is indicated that only portions are dispensed in paragraph [0026]; reaction device is discussed at paragraph [0003] as state of the art);**

drawing the remaining volume of fluid upwardly into the confines of said tip, said remaining volume being the difference between said initial volume and the volume of said dispensed portions into said axial portion of said tip, said tip including at least one stepped area above immediately above said read window to latch an upper meniscus of said retained fluid volume to flatten said meniscus to permit an accurate optical reading of said retained fluid volume (**support is provided at paragraphs [0026], [0027] and in particular at paragraphs [0029] and [0030].**

Claim 17 has been canceled.

For the foregoing reasons, it is believed the subject matter of each of the rejected claims is clearly supported by the as-filed patent application, including the drawings. Reconsideration is respectfully requested.

In summary and in view of the above amendment, Applicant believes the above-captioned application is now in a condition for allowance and an expedited Notice of Allowability is earnestly solicited.

If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicant's representative at the telephone number listed below.

It is believed no fees are required for the filing of this response. However, in the event that any additional fees are required, the Director is hereby authorized to charge Deposit Account No. 50-3010 for any additional fees and to charge any overpayments thereto.

Respectfully submitted,

HISCOCK & BARCLAY, LLP

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A handwritten signature in black ink, appearing to read 'Peter J. Bilinski', is written over a horizontal line.

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